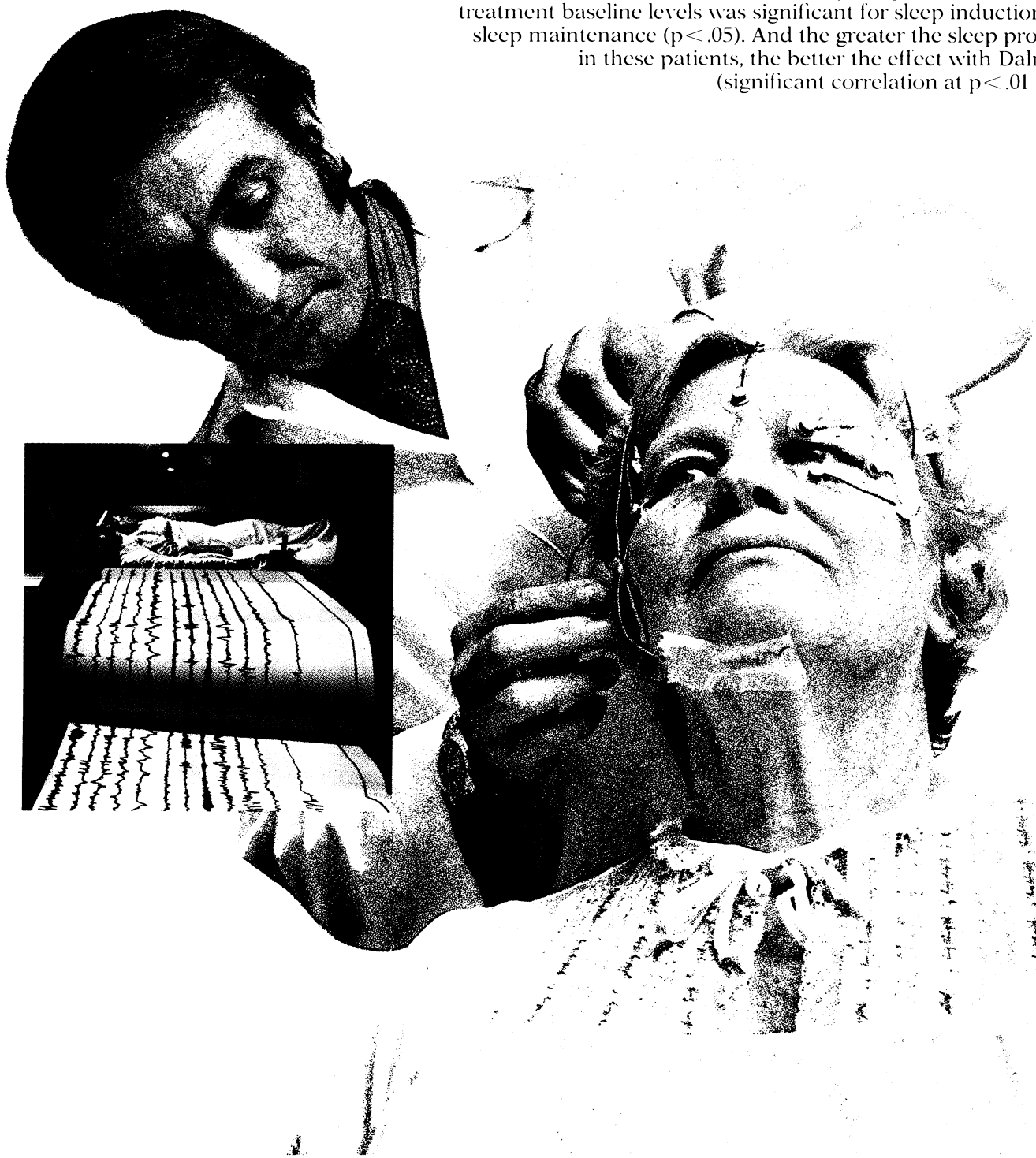
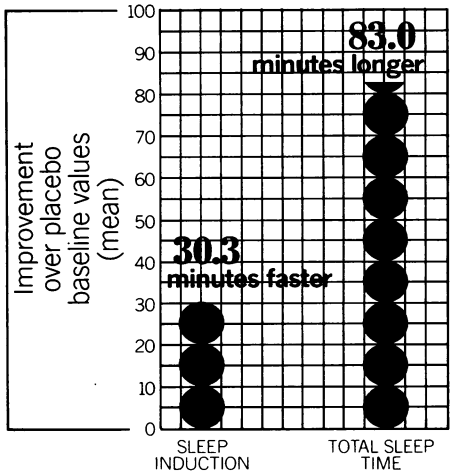
# The ultimate objective test: sleep laboratory proof of effectiveness... now in geriatric insomnia patients

Six female insomniacs, ranging in age from 67 to 82 years, received Dalmane (flurazepam HCl) for seven consecutive nights in the sleep research laboratory.[1] Improvement over pre-treatment baseline levels was significant for sleep induction and sleep maintenance ($p < .05$). And the greater the sleep problem in these patients, the better the effect with Dalmane (significant correlation at $p < .01$ level).



## Elderly insomniacs fell asleep faster, slept longer[1]




## Results expand and confirm objective proof of efficacy in younger adults with insomnia

The effectiveness of Dalmane (flurazepam HCl) was demonstrated in earlier studies of 32 younger adults with trouble falling asleep, staying asleep or sleeping long enough.[2] On average, in these studies, Dalmane induced sleep within 17 minutes and provided 7 to 8 hours of sleep, at the same time reducing number of nighttime awakenings.

## Relative safety, even in patients on warfarin

Morning "hang-over" has been relatively infrequent with Dalmane. And no unacceptable fluctuation in prothrombin time has been reported in warfarin patients on Dalmane.[2,3] The usual adult dosage is 30 mg *h.s.*; in elderly and debilitated patients, limit initial dosage to 15 mg to help preclude oversedation, dizziness or ataxia.

**Before prescribing Dalmane (flurazepam HCl), please consult complete product information, a summary of which follows:**

**Indications:** Effective in all types of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakening; in patients with recurring insomnia or poor sleeping habits; and in acute or chronic medical situations requiring restful sleep. Since insomnia is often transient and intermittent, prolonged administration is generally not necessary or recommended.

**Contraindications:** Known hypersensitivity to flurazepam HCl.

**Warnings:** Caution patients about possible combined effects with alcohol and other CNS depressants. Caution against hazardous occupations requiring complete mental alertness (*e.g.*, operating machinery, driving). Use in women who are or may become pregnant only when potential benefits have been weighed against possible hazards. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage.

**Precautions:** In elderly and debilitated, initial dosage should be limited to 15 mg to preclude oversedation, dizziness and/or ataxia. If combined with other drugs having hypnotic or CNS-depressant effects, consider potential additive effects. Employ usual precautions in patients who are severely depressed, or with latent depression or suicidal tendencies. Periodic blood counts and liver and kidney function tests are advised during repeated therapy. Observe usual precautions in presence of impaired renal or hepatic function.

**Adverse Reactions:** Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported were headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins and alkaline phosphatase. Paradoxical reactions, *e.g.*, excitement, stimulation and hyperactivity, have also been reported in rare instances.

**Dosage:** Individualize for maximum beneficial effect. *Adults:* 30 mg usual dosage; 15 mg may suffice in some patients. *Elderly or debilitated patients:* 15 mg initially until response is determined.

**Supplied:** Capsules containing 15 mg or 30 mg flurazepam HCl.


**REFERENCES:**

1. Frost JD Jr: Data on file, Medical Department, Hoffmann-La Roche Inc., Nutley NJ
2. Data on file, Medical Department, Hoffmann-La Roche Inc., Nutley NJ
3. Robinson DS, Amidon EL: Interaction of benzodiazepines with warfarin in man, in *The Benzodiazepines*, edited by Garattini S, Mussini E, Randall LO. New York, Raven Press, 1973, p. 641


# New evidence proves insomnia relief in elderly patients

# Dalmane®
## (flurazepam HCl) C-IV

**One 15-mg capsule *h.s.*—initial dosage for elderly or debilitated patients.**
**One 30-mg capsule *h.s.*—usual adult dosage**
(15 mg may suffice in some patients).

## For all common types of insomnia

ROCHE

ROCHE LABORATORIES
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

# How many of your patients know what protein is?

## But they do know what meat is.

The foods above have several nutrients in common. They include cell-building protein, as well as niacin, iron and thiamin. Because of these common nutrients, these foods are considered a part of the Meat Group in the U.S. Department of Agriculture's Four Food Groups system.

Some physicians counsel patients in terms of nutrients. Which is easier for them to understand—foods or nutrients?

For attractive, color copies of the Four Food Groups guide for your patients, write: Dairy Council of California, Box 28F, Sacramento, CA 95825.

Dairy Council of California

*The Four Food Groups—milk, meat, vegetables and fruits, breads and cereals—a practical guide to good nutrition.*

The menopausal "flush" is believed to result from an autonomic nervous system imbalance due to estrogen deficiency. Here, illustration shows artist's interpretation of "normal" vs. dilated arteriole-capillary-venule network.

**"It seemed like I was having one flush after another. It wasn't just a nuisance... it was a real problem."**

# The menopausal flush is the classic sign of estrogen deficiency...generally recognized as a clear indication for treatment.

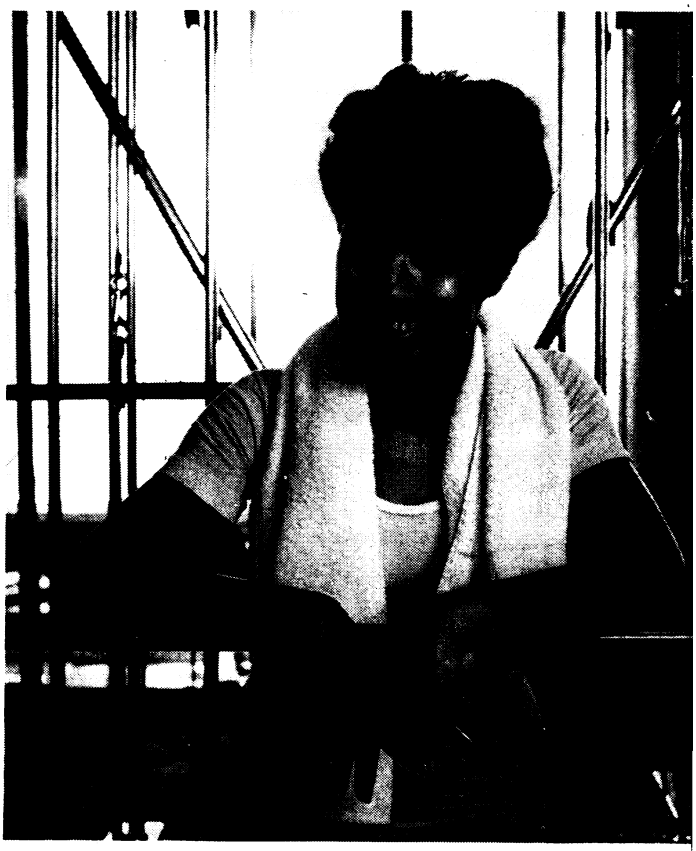
This wasn't always the case.

There was a time when the symptoms of the menopause went untreated...when women were expected to suffer the severe flushes and sweats of estrogen deficiency in silence or, at best, with a minimum of encouragement and understanding.

Now, with effective estrogen replacement therapy, women do not have to endure these distressing symptoms. In the great majority of cases, PREMARIN (Conjugated Estrogens Tablets, U.S.P.) can promptly control such vasomotor symptomatology...provide classic relief for classic symptoms during a troublesome period of physiologic adjustment.

*Three studies have reported an increased risk of endometrial carcinoma in association with the postmenopausal administration of exogenous estrogens. For further information see "Warnings" in prescribing information.*

**"The flushes were bad enough... but the sweats at night were almost too much."**



# For the classic symptoms of the menopause

# PREMARIN®

## (CONJUGATED ESTROGENS TABLETS, U.S.P.)

CONTAINS NATURAL ESTROGENS EXCLUSIVELY

*See next page for revised prescribing information.*

BRIEF SUMMARY
*(For full prescribing information, see package circular.)*
**PREMARIN® Brand of**
**CONJUGATED ESTROGENS TABLETS, U.S.P.**

**Actions:** Estrogens are responsible for development and maintenance of the female reproductive system and secondary sex characteristics. They cause the growth and development of the vagina, uterus, and fallopian tubes, and enlargement of the breasts. Indirectly, they contribute to the shaping of the skeleton, maintenance of tone and elasticity of urogenital structures, changes in the epiphyses of the long bones that allow for pubertal growth spurt and termination, growth of axillary and pubic hair, and pigmentation of the nipples and genitals. Estrogens are also involved in psychologic and emotional aspects of feminine behavior. As estrogen levels increase during the menstrual cycle, there is a sense of vigor and well-being, and in the menopausal period estrogens aid in relieving nervous symptoms (*e.g.* anxiety, depression and irritability) due to estrogen deficiency. Decline of estrogenic activity at the end of the menstrual cycle can bring on menstruation, although the cessation of progesterone secretion is the most important factor in the mature ovulatory cycle. However, in the pre- or non-ovulatory cycle, estrogen is the primary determinant in the onset of menstruation. Estrogens do not induce ovulation.

Estrogens affect calcium and phosphorus metabolism, and are involved in maintenance of normal bone structure. In prolonged estrogen deficiency states, administration of estrogen acts to prevent associated bone degenerative changes.

Estrogens appear to be responsible for the relatively greater amount of alpha-lipoprotein and correspondingly lower amount of beta-lipoprotein found in premenopausal women as compared with men.

Estrogens affect the release of pituitary gonadotropins and may also deplete the gonadotropic content of the pituitary.

**Indications:** Based on a review of PREMARIN Tablets by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications for use as follows:
**Effective:** As replacement therapy for naturally occurring or surgically induced estrogen deficiency states associated with: the climacteric, including the menopausal syndrome and postmenopause; senile vaginitis and kraurosis vulvae, with or without pruritus.
**"Probably" effective:** For estrogen deficiency-induced osteoporosis, and only when used in conjunction with other important therapeutic measures such as diet, calcium, physiotherapy, and good general health-promoting measures. Final classification of this indication requires further investigation.

**Contraindications:** Short acting estrogens are contraindicated in patients with (1) markedly impaired liver function; (2) known or suspected carcinoma of the breast, except those cases of progressing disease not amenable to surgery or irradiation occurring in women who are at least 5 years postmenopausal; (3) known or suspected estrogen-dependent neoplasia, such as carcinoma of the endometrium; (4) thromboembolic disorders, thrombophlebitis, cerebral embolism, or in patients with a past history of these conditions; (5) undiagnosed abnormal genital bleeding.

**Warnings:** Three separate studies have reported an increased risk of endometrial carcinoma in association with the postmenopausal administration of exogenous estrogens. Smith *et al.*[1] retrospectively compared the records of 317 patients with endometrial carcinoma with the records of an equal number of contrast patients having cervical, ovarian, or vulvar neoplasms. The unadjusted relative risk estimate of endometrial cancer was 4.5 times greater in women exposed to estrogen therapy. The type of estrogen used, the preparation, and the dosage were not considered in this study. These factors may play a role in modifying the average relative risk found in this study. The authors also suggested that there may be a relationship between increasing risk and the duration of administration; however, the data are not conclusive on this point. A second retrospective study reported by Ziel and Finkle[2] examined the records of 94 patients with endometrial carcinoma and those of a two-fold contrast series from the same health plan population. The estimate of relative risk was found to be 7.6. In addition, the authors reported a relative risk estimate of 5.6 for a duration of exposure of 1 to 4.9 years, and 13.9 for exposure of 7 or more years. In this study, conjugated estrogens were reported to be the type of estrogen used. Mack *et al.*[3] retrospectively studied 63 cases of endometrial carcinoma and a four-fold contrast group. The relative risk of endometrial carcinoma was estimated to be 8.0 for any estrogen usage, and 5.6 for conjugated estrogen usage. The relationship between relative risk and duration of use could not be conclusively described from the data in the study.

Estrogen therapy should not be given to women with recurrent chronic mastitis or abnormal mammograms except, if in the opinion of the physician, it is warranted despite the possibility of aggravation of the mastitis or stimulation of undiagnosed estrogen-dependent neoplasia.

The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, retinal thrombosis, cerebral embolism and pulmonary embolism). If these occur or are suspected, estrogen therapy should be discontinued immediately.

Estrogens may be excreted in the mother's milk and an estrogenic effect upon the infant has been described. The long range effect on the nursing infant cannot be determined at this time.

Hypercalcemia may occur in as many as 15 percent of breast cancer patients with metastases, and this usually indicates progression of bone metastases. This occurrence depends neither on dose nor on immobilization. In the presence of progression of the cancer or hypercalcemia, estrogen administration should be stopped.

A statistically significant association has been reported between maternal ingestion of diethylstilbestrol during pregnancy and the occurrence of vaginal carcinoma in the offspring. This occurred with the use of diethylstilbestrol for the treatment of threatened abortion or high risk pregnancies. Whether or not such an association is applicable to all estrogens is not known at this time. In view of this finding, however, the use of any estrogen in pregnancy is not recommended.

Failure to control abnormal uterine bleeding or unexpected recurrence is an indication for curettage.

**Precautions:** As with all short acting estrogens, the following precautions should be observed:

A complete pretreatment physical examination should be performed with special reference to pelvic and breast examinations. Such physical examinations should be repeated at regular intervals, at least annually, during estrogen therapy.

To avoid prolonged stimulation of the endometrium and breasts in climacteric or hypogonadal women, estrogens should be administered cyclically (3 week regimen with 1 week rest period—withdrawal bleeding may occur during rest period).

Because of individual variation in endogenous estrogen production, relative overdosage may occur which could cause undesirable effects such as abnormal or excessive uterine bleeding, mastodynia and edema.

Because of salt and water retention associated with estrogenic anabolic activity, estrogens should be used with caution in patients with epilepsy, migraine, asthma, cardiac, or renal disease.

If unexplained or excessive vaginal bleeding should occur, reexamination should be made for organic pathology.

Estrogen usage may cause preexisting fibromyomata to increase in size; therefore, patients should be examined at regular intervals while receiving estrogenic therapy.

The pathologist should be advised of estrogen therapy when relevant specimens are submitted.

Because of their effects on epiphyseal closure, estrogens should be used judiciously in young patients in whom bone growth is incomplete.

Prolonged high dosages of estrogens will inhibit anterior pituitary functions. This should be borne in mind when treating patients in whom fertility is desired.

The age of the patient constitutes no absolute limiting factor, although treatment with estrogens may mask the onset of the climacteric.

Certain liver and endocrine function tests may be affected by exogenous estrogen administration. If test results are abnormal in a patient taking estrogen, they should be repeated after estrogen has been withdrawn for one cycle.

**Adverse Reactions:** The following adverse reactions have been reported associated with short acting estrogen administration:
nausea, vomiting, anorexia
gastrointestinal symptoms such as abdominal cramps and bloating
increased incidence of gallbladder disease
breakthrough bleeding, spotting, unusually heavy withdrawal bleeding (See DOSAGE AND ADMINISTRATION)
breast tenderness and enlargement
reactivation of endometriosis
possible diminution of lactation when given immediately postpartum
loss of libido and gynecomastia in males
edema
aggravation of migraine headaches
change in body weight (increase, decrease)
headache
allergic rash
hepatic cutaneous porphyria becoming manifest

**Dosage and Administration:** PREMARIN (Conjugated Estrogens Tablets, U.S.P.) should be administered cyclically (3 weeks of daily estrogen and 1 week off). There should be an annual reassessment of the patient to determine the need for continued estrogen therapy. This assessment may be assisted by lowering the dose and observing the symptoms to determine correct maintenance dosage for continued therapy.

*Menopausal Syndrome*—1.25 mg daily, cyclically. Adjust dosage upward or downward according to severity of symptoms and response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control.

If the patient has not menstruated within the last two months or more, cyclic administration is started arbitrarily. If the patient is menstruating, cyclic administration is started on day 5 of bleeding. If breakthrough bleeding (bleeding or spotting during estrogen therapy) occurs, increase estrogen dosage as needed to stop bleeding. In the following cycle, employ the dosage level used to stop breakthrough bleeding in the previous cycle. In subsequent cycles, the estrogen dosage is gradually reduced to the lowest level which will maintain the patient symptom-free.

*Postmenopause*—as a protective measure against estrogen deficiency-induced degenerative changes (*e.g.* osteoporosis, atrophic vaginitis, kraurosis vulvae)—0.3 mg to 1.25 mg daily and cyclically. Adjust dosage to lowest effective level.

*Osteoporosis* (to retard progression)—usual dosage 1.25 mg daily and cyclically.

*Senile Vaginitis, Kraurosis Vulvae with or without Pruritus*—0.3 mg to 1.25 mg or more daily, depending upon the tissue response of the individual patient. Administer cyclically.

**How Supplied:** PREMARIN (Conjugated Estrogens Tablets, U.S.P.)
No. 865—Each *purple* tablet contains 2.5 mg, in bottles of 100 and 1,000.
No. 866—Each *yellow* tablet contains 1.25 mg, in bottles of 100 and 1,000. Also in unit dose package of 100.
No. 867—Each *red* tablet contains 0.625 mg, in bottles of 100 and 1,000. Also in unit dose package of 100.
No. 868—Each *green* tablet contains 0.3 mg, in bottles of 100 and 1,000.

**References:** 1. Smith, D.C., Prentice, R., Thompson, D.J., and Herrmann, W.L.: Association of exogenous estrogen and endometrial carcinoma, N. Engl. J. Med. *293*:1164-1167, 1975. 2. Ziel, H.K., and Finkle, W.D.: Increased risk of endometrial carcinoma among users of conjugated estrogens, N. Engl. J. Med. *293*:1167-1170, 1975. 3. Mack, T.M., Pike, M.C., Henderson, B.E., Pfeffer, R.I., Gerkins, V.R., Arthur, M., and Brown, S.: Estrogens and endometrial cancer in a retirement community, submitted for publication.
**7643**

Ayerst. AYERST LABORATORIES
New York, N.Y. 10017

# PREMARIN®
# (CONJUGATED ESTROGENS TABLETS, U.S.P.)
# contains natural estrogens exclusively

# his man has a ranch in Montana, a condominium n Hawaii, and over $300,000 in earning assets. Why would he need a Living Trust?

## For the same reason you do.

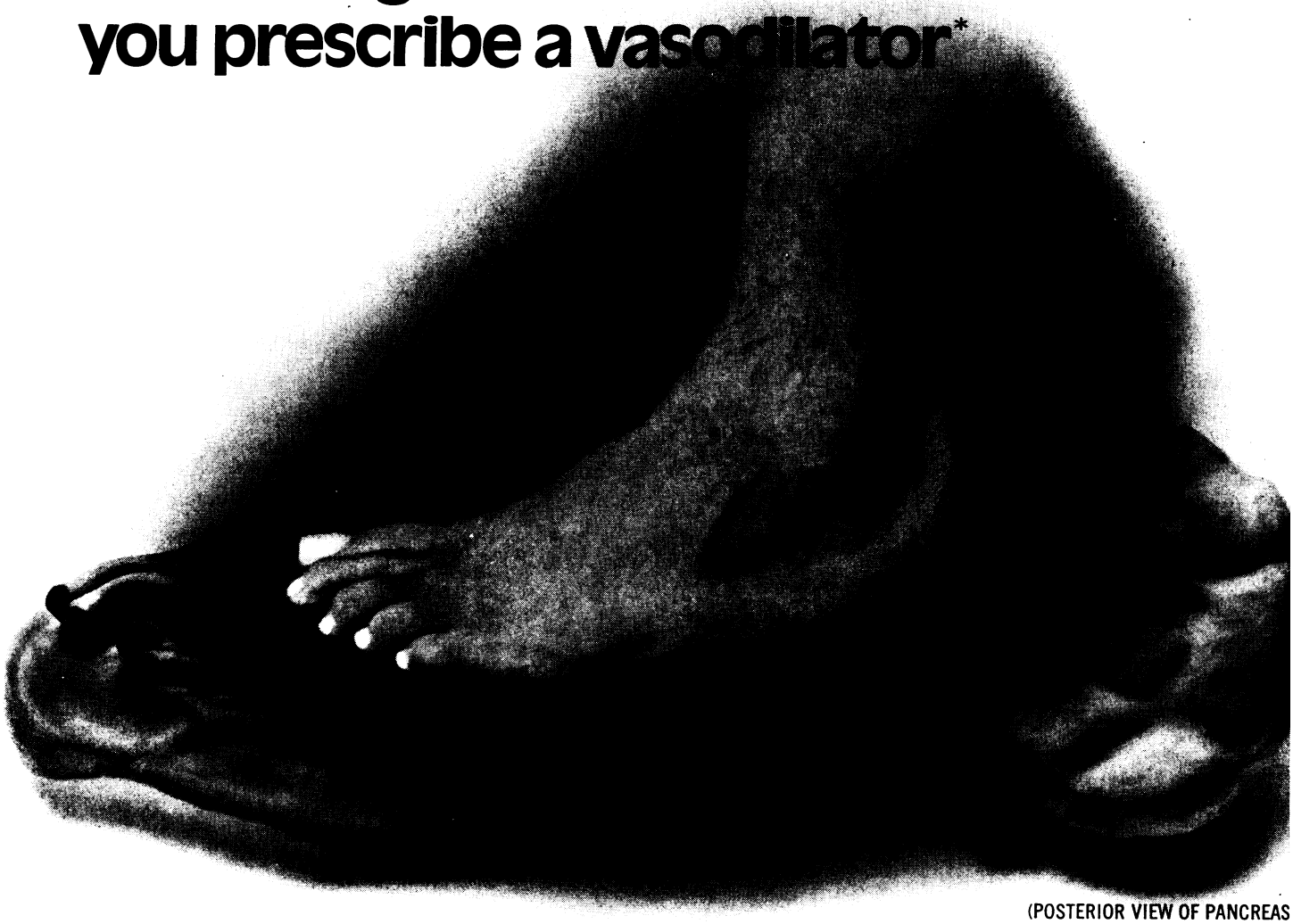
It's one of the ironies of life that e last person who would appear to ed a Living Trust, needs it most. The n above, for example, or you. cause the more successful you are at naging your business affairs, the s time you necessarily have to vote to the day-to-day management your personal finances. And that's ere a Living Trust comes in.

Unlike ordinary trusts set aside for future, a Living Trust is in effect here and now. It's designed to help you benefit in the present: by providing expert management of your investments, real estate, securities, taxes—all aspects of your personal finances that need looking after, while you're busy looking after business. A team of specialists is assigned to your account for watchful guidance and fast, knowledgeable decision-making. They can balance your books, help you save on income taxes and professional fees, and suggest ways to improve your estate while you're still around to enjoy it.

The more successful you are, the more reason you have to take advantage of a Living Trust. Stop in and talk with one of our Bank of America Trust Officers. He'll convince you, if this hasn't. Depend on us. More Californians do.

BANK OF AMERICA
Trust Department

# consider the effect on coexisting diabetes when you prescribe a vasodilator*



(POSTERIOR VIEW OF PANCREAS

## no interference in the management of the diabetic patient has been reported with

# VASODILAN®
## (ISOXSUPRINE HCl)

TABLETS, 20 mg.

## the compatible vasodilator

***Indications:** Based on a review of this drug by the National Academy of Sciences-National Research Council and/or other information, the FDA has classified the indications as follows:

Possibly Effective:

1. For the relief of symptoms associated with cerebral vascular insufficiency.
2. In peripheral vascular disease of arteriosclerosis obliterans, thromboangiitis obliterans (Buerger's Disease) and Raynaud's disease.
3. Threatened abortion.

Final classification of the less-than-effective indications requires further investigation.

**Composition:** Vasodilan tablets, isoxsuprine HCl, 10 mg. and 20 mg.

**Dosage and Administration:** 10 to 20 mg. three or four times daily.

**Contraindications and Cautions:** There are no known contraindications to oral use when administered in recommended doses. Should not be given immediately postpartum or in the presence of arterial bleeding.

**Adverse Reactions:** On rare occasions, oral administration of the drug has been associated in time with the occurrence of severe rash. When rash appears, the drug should be discontinued. Occasional overdosage effects such as transient palpitation or dizziness are usually controlled by reducing the dose.

**Supplied:** Tablets, 10 mg.—bottles of 100, 1000, 5000 and Unit Dose; 20 mg.—bottles of 100, 500, 1000, 5000 and Unit Dose.

Mead Johnson LABORATORIES

 MJL-54117

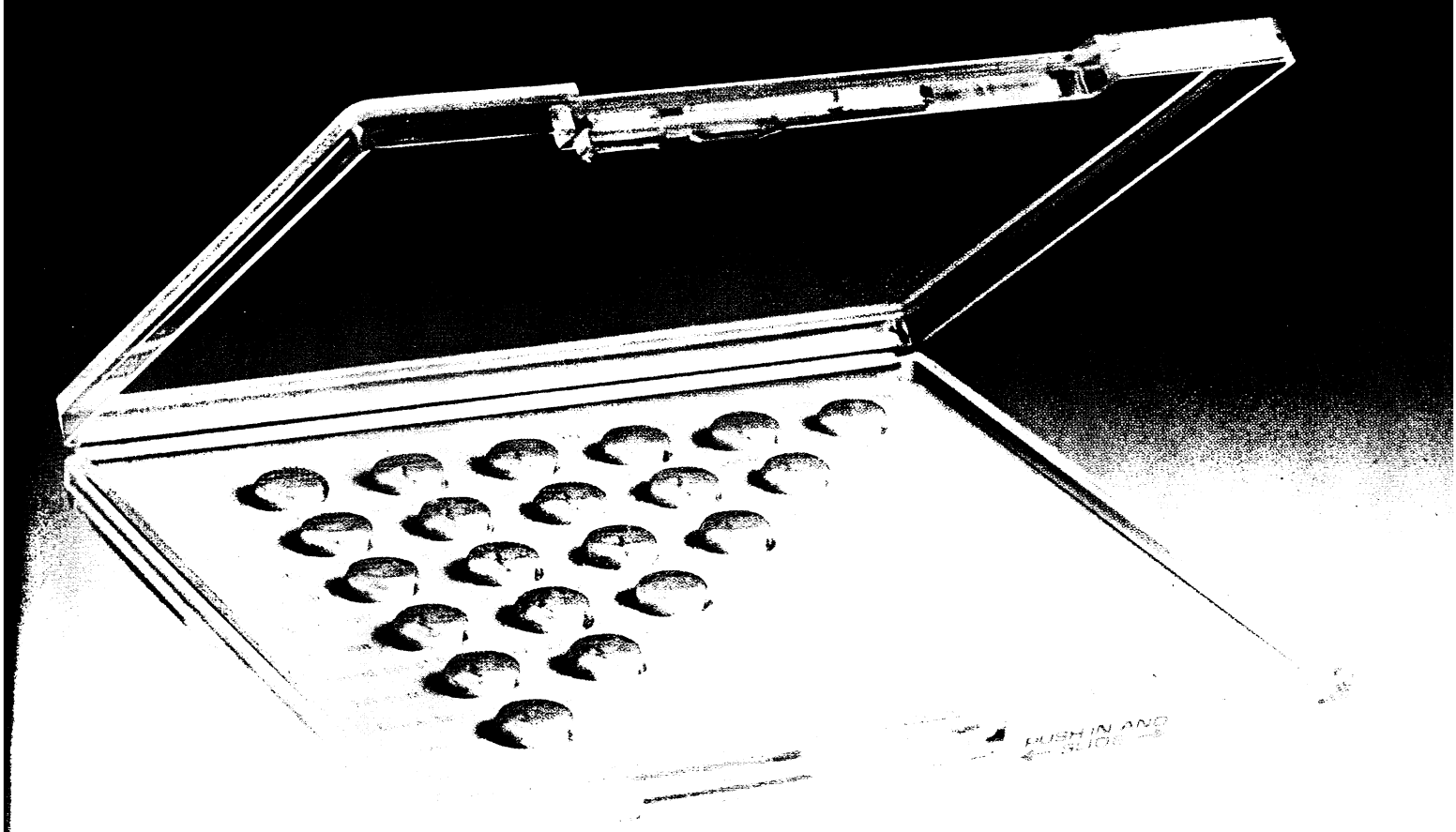
**Upjohn**

The Upjohn Company, Kalamazoo, Michigan 49001

# Medrol® 4 mg Dosepak*

methylprednisolone, Upjohn

The explicit printed dosage instructions that accompany each Dosepak make it easy for the patient to understand and follow the dosage regimen.



# Testing in Humans: Who, Where & When.

## The weight of ethical opinion:

Few would disagree that the effectiveness and safety of any therapeutic agent or device must be determined through clinical research.

But now the *practice* of clinical research is under appraisal by Congress, the press and the general public. Who shall administer it? On whom are the products to be tested? Under what circumstances? And how shall results be evaluated and utilized?

The Pharmaceutical Manufacturers Association represents firms that are significantly engaged in the discovery and development of new medicines, medical devices and diagnostic products. Clinical research is essential to their efforts. Consequently, PMA formulated positions which it submitted on July 11, 1975, to the Subcommittee on Health of the Senate Labor and Public Welfare Committee, as its official policy recommendations. Here are the essentials of PMA's current thinking in this vital area.

**1.** PMA supports the mandate and mission of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and offers to establish a special committee composed of experts of appropriate disciplines familiar with the industry's research methodology to volunteer its service to the Commission.

**2.** PMA supports the formation of an independent, expert, broadly based and representative panel to assess the current state of drug innovation and the impact upon it of existing laws, regulations and procedures.

**3.** When FDA proposes regulations, it should prepare and publish in the *Federal Register* a detailed statement assessing the impact of those regulations on drug and device innovation.

**4.** PMA proposes that an appropriately qualified medical organization be encouraged to undertake a comprehensive study of the optimum roles and responsibilities of the sponsor and physician when company-sponsored clinical research is performed by independent clinical investigators.

**5.** PMA recognizes that the physician-investigator has, and should have, the ultimate responsibility for deciding the substance and form of the informed consent to be obtained. However, PMA recommends that the sponsor of the experiment aid the investigator in discharging this important responsibility by providing (1) a document detailing the investigator's responsibilities under FDA regulations with regard to patient consent, and (2) a written description of the relevant facts about the investigational item to be studied, in comprehensible lay language.

**6.** In the case of children, the sponsor must require that informed consent be obtained from a legally appropriate representative of the participant. Voluntary consent of an older child, who may be capable of understanding, in addition to that of a parent, guardian or other legally responsible person, is advisable. Safety of the drug or device shall have been assessed in adult populations prior to use in children.

**7.** PMA endorses the general principle that, in the case of the mentally infirm, consent should be sought from both an understanding subject and from a parent or guardian, or in their absence, another legally responsible person.

**8.** Pharmaceutical manufacturers sponsoring investigations in prisons must take all reasonable care to assure that the facilities and personnel used in the conduct of the investigations are suitable for the protection of participants, and for the avoidance of coercion, with a respect for basic humanitarian principles.

**9.** Sponsors intending to conduct non-therapeutic clinical trials through the participation of employee volunteers should expand the membership and scope of its existing Medical Research Committee, or establish such an internal Medical Research Committee, with responsibility to approve the consent forms of all volunteers, designs, protocols and the scope of the trial. The Committee should also bear responsibility to ensure full compliance with all procedures intended to protect employee volunteers' rights.

**10.** Where the sponsor obtains medical information or data on individuals, it shall be accorded the same confidential status as provided in codes of ethics governing health care professionals.

**11.** PMA and its member firms accept responsibility to aid and encourage appropriate follow-up of human subjects who have received investigational products that cause latent toxicity in animals or, during their use in clinical investigation, are found to cause unexpected and serious adverse effects.

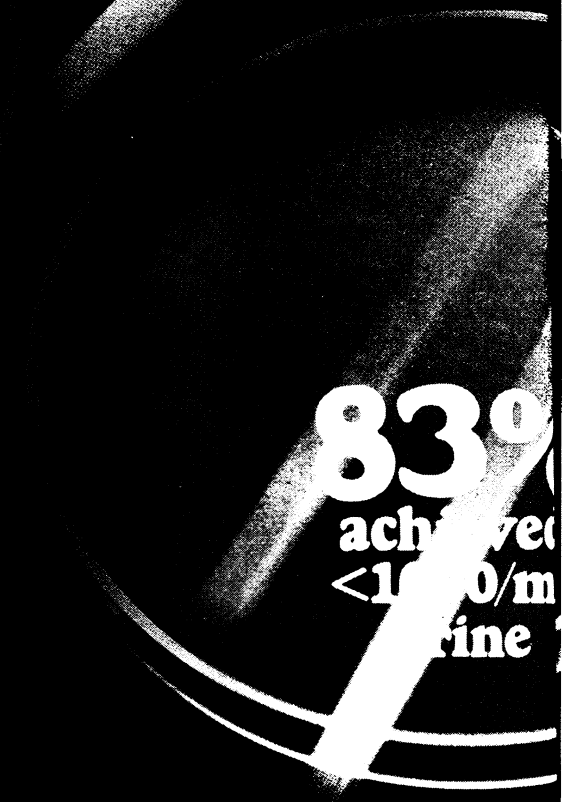
**12.** PMA supports the exploration and development by its member companies of more systematic surveillance procedures for newly marketed products.

**13.** When a pharmaceutical manufacturer concludes, on the basis of early clinical trials of a basic new agent, that a new drug application is likely to be submitted, a proposed development plan accompanied by a summary of existing data, would be submitted to the FDA. Following a review of this submission, the FDA, and its Advisory Committee where appropriate, would meet with the sponsor to discuss the development plan. No *formal* FDA approval should be required at this stage. Rather, the emphasis should be on identification of potential problems and questions for the sponsor's further study and resolution as the program develops.

The PMA believes that health professionals as well as the public at large should be made aware of these 13 points in its Policy on Clinical Research. For these recommendations envisage constructive, cooperative action by industry, research institutions, the health professions and government to encourage creative and workable responses to issues involved in the clinical investigation of new products.

PMA
Pharmaceutical Manufacturers Association
1155 Fifteenth Street, N.W.
Washington, D. C. 20005

# However you defin
# in acute cystiti
# achieved ar


*In a new study 8 out of 10 patients with acute lower urinary tract infection, primarily cystitis, achieved sterile urine. All infections were nonobstructed. Susceptible organisms included *E. coli, Klebsiella-Aerobacter, Proteus mirabilis* and *Proteus vulgaris*.

| No. of patients | Sterile urine | Clear culture <1000 organisms/ml urine | Clear culture <10,000 organisms/ml urine |
|---|---|---|---|
| 406 | 81% (330) | 83% (339) | 88% (357) |

Data on file, Hoffmann-La Roche Inc., Nutley, New Jersey

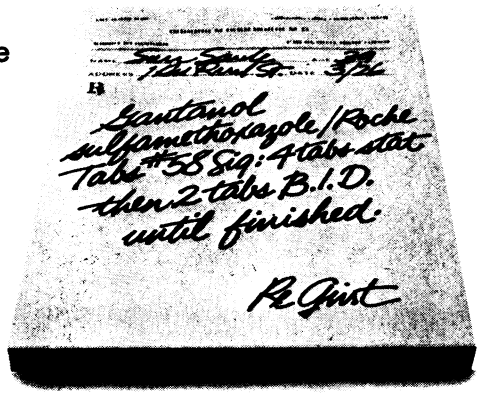

B.I.D.
81% to 88% cure rate*
88%
achieved
<100,000/ml
urine
Gantanol® B.I.D.
sulfamethoxazole/Roche
4 tablets (0.5 Gm each) STAT—then 2 tablets B.I.D. for 10-14 days
Basic therapy with convenience and economy
in acute nonobstructed cystitis†
†due to susceptible organisms
ROCHE
Please see following page for summary of product information.

# Gantanol® B.I.D.
## sulfamethoxazole/Roche

## Basic therapy with convenience and economy in acute nonobstructed cystitis*

4 tablets (0.5 Gm each) STAT—then 2 tablets B.I.D. for 10-14 days

- ☐ Effective in nonobstructed cystitis.
- ☐ Active against susceptible strains of gram-negative and gram-positive organisms: *E. coli, Klebsiella-Aerobacter, Staph. aureus, Proteus mirabilis* and, less frequently, *Proteus vulgaris.*
- ☐ Rapid antibacterial blood and urine levels—in from 2 to 3 hours.
- ☐ Convenient, economical B.I.D. dosage.
- ☐ Contraindicated during pregnancy and the nursing period and in infants under 2 months of age.
- ☐ As with all sulfonamides, adequate fluid intake should be maintained during therapy; perform frequent CBC's and urinalyses with careful microscopic examination.




*due to susceptible organisms

**Before prescribing, please consult complete product information, a summary of which follows:**

**Indications:** Acute, recurrent or chronic nonobstructed urinary tract infections (primarily nonobstructed pyelonephritis, pyelitis and cystitis) due to susceptible organisms, usually *E. coli, Klebsiella-Aerobacter, Staphylococcus aureus, Proteus mirabilis* and, less frequently, *Proteus vulgaris.* **Note: Carefully coordinate *in vitro* sulfonamide sensitivity tests with bacteriologic and clinical response; add aminobenzoic acid to follow-up culture media. The increasing frequency of resistant organisms limits the usefulness of antibacterials including sulfonamides, especially in chronic or recurrent urinary tract infections.** Measure sulfonamide blood levels as variations may occur; 20 mg/100 ml should be maximum total level.

**Contraindications:** Sulfonamide hypersensitivity; pregnancy at term and during nursing period; infants less than two months of age.

**Warnings:** Safety during pregnancy has not been established. Sulfonamides should not be used for group A beta-hemolytic streptococcal infections and will not eradicate or prevent sequelae (rheumatic fever, glomerulonephritis) of such infections. Deaths from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias have been reported and early clinical signs (sore throat, fever, pallor, purpura or jaundice) may indicate serious blood disorders. Frequent CBC and urinalysis with microscopic examination are recommended during sulfonamide therapy. Insufficient data on children under six with chronic renal disease.

**Precautions:** Use cautiously in patients with impaired renal or hepatic function, severe allergy, bronchial asthma; in glucose-6-phosphate dehydrogenase-deficient individuals in whom dose-related hemolysis may occur. Maintain adequate fluid intake to prevent crystalluria and stone formation.

**Adverse Reactions:** *Blood dyscrasias* (agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia); *allergic reactions* (erythema multiforme, skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis); *gastrointestinal reactions* (nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis); *CNS reactions* (headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia); *miscellaneous reactions* (drug fever, chills, toxic nephrosis with oliguria and anuria, periarteritis nodosa and L.E. phenomenon). Due to certain chemical similarities with some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia as well as thyroid malignancies in rats following long-term administration. Cross-sensitivity with these agents may exist.

**Dosage: Systemic sulfonamides are contraindicated in infants under 2 months of age** (except adjunctively with pyrimethamine in congenital toxoplasmosis).

*Usual adult dosage:* 2 Gm (4 tabs or teasp.) initially, then 1 Gm *b.i.d.* or *t.i.d.* depending on severity of infection.

*Usual child's dosage:* 0.5 Gm (1 tab or teasp.)/20 lbs of body weight initially, then 0.25 Gm/20 lbs *b.i.d.* Maximum dose should not exceed 75 mg/kg/24 hrs.

**Supplied:** *Tablets, 0.5 Gm sulfamethoxazole; Suspension,* 0.5 Gm sulfamethoxazole/teaspoonful.

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# IN GONORRHEA

## INJECTION Wycillin® (STERILE PENICILLIN G PROCAINE SUSPENSION) WYETH

In **Gonorrhea,** the drug regimen of choice is aqueous penicillin G procaine. In uncomplicated cases, administration of 4.8 million units together with 1 gram oral probenecid, given just before injection, is recommended.

**Indications:** In treatment of moderately severe infections due to penicillin G-sensitive microorganisms sensitive to the low and persistent serum levels common to this particular dosage form. Therapy should be guided by bacteriological studies (including sensitivity tests) and by clinical response.

**NOTE:** When high sustained serum levels are required use aqueous penicillin G, IM or IV.

The following infection will usually respond to adequate dosages of intramuscular penicillin G procaine—*N. gonorrhoeae:* acute and chronic (without bacteremia).

**For deep intramuscular injection only.**

**Contraindication:** Previous hypersensitivity reaction to any penicillin.

**Warnings: Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen and intravenous corticosteroids should also be administered as indicated.**

**Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more apt to occur in individuals with a history of sensitivity to multiple allergens.**

**There have been well-documented reports of individuals with a history of penicillin hypersensitivity reactions who have experienced severe hypersensitivity reactions when treated with a cephalosporin. Before therapy with a penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, and other allergens. If an allergic reaction occurs, the drug should be discontinued and the patient treated with the usual agents, e.g., pressor amines, antihistamines, and corticosteroids.**

**Immediate toxic reactions to procaine may occur in some individuals, particularly when a large single dose is administered in the treatment of gonorrhea (4.8 million units). These reactions may be manifested by mental disturbances, including anxiety, confusion, agitation, depression, weakness, seizures, hallucinations, combativeness, and expressed "fear of impending death". The reactions noted in carefully controlled studies occurred in approximately one in 500 patients treated for gonorrhea. Reactions are transient, lasting from 15-30 minutes.**

**Precautions:** Use cautiously in individuals with histories of significant allergies and/or asthma.

Carefully avoid intravenous or intraarterial use, or injection into or near major peripheral nerves or blood vessels, since such injections may produce neurovascular damage.

A small percentage of patients are sensitive to procaine. If there is a history of sensitivity, make the usual test: Inject intradermally 0.1 ml. of a 1 to 2 percent procaine solution. Development of an erythema, wheal, flare or eruption indicates procaine sensitivity. Sensitivity should be treated by the usual methods including barbiturates, and procaine penicillin preparations should not be used. Antihistaminics appear beneficial in treatment of procaine reactions.

The use of antibiotics may result in overgrowth of nonsusceptible organisms. Constant observation of the patient is essential. If new infections due to bacteria or fungi appear during therapy, discontinue penicillin and take appropriate measures.

If allergic reaction occurs, withdraw penicillin unless in the opinion of the physician, the condition being treated is life threatening and amenable only to penicillin therapy.

When treating gonococcal infections with suspected primary or secondary syphilis, perform proper diagnostic procedures including darkfield examinations. In all cases in which concomitant syphilis is suspected, perform monthly serological tests for at least four months.

**Adverse Reactions:** (Penicillin has significant index of sensitization) skin rashes, ranging from maculopapular eruptions to exfoliative dermatitis; urticaria; serum sickness-like reactions including chills, fever, edema, arthralgia and prostration. Severe and often fatal anaphylaxis has been reported. (See "Warnings.")

As with other antisyphilitics, Jarisch-Herxheimer reaction has been reported.

Procaine toxicity manifestations have been reported (see "Warnings"). Procaine hypersensitivity reactions have not been reported with this drug.

**Dosage and Administration:** Administer only by *deep intramuscular injection,* in upper outer quadrant of buttock. In infants and small children, midlateral aspect of thigh may be preferable. When doses are repeated, vary injection site. Before injection aspirate to be sure needle bevel is not in blood vessel. If blood appears, remove needle and inject in another site.

Although some isolates of *Neisseria gonorrhoeae* have decreased susceptibility to penicillin, this resistance is relative, not absolute, and penicillin in large doses remains the drug of choice. Physicians are cautioned not to use less than recommended doses.

Gonorrheal infections (uncomplicated)—Men or Women: 4.8 million units intramuscularly divided into at least two doses and injected at different sites at one visit, together with 1 gram of oral probenecid, given just before injection.

**NOTE:** Treatment of severe complications of gonorrhea should be individualized using large amounts of short-acting penicillin. Gonorrheal endocarditis should be treated intensively with aqueous penicillin G. Prophylactic or epidemiologic treatment for gonorrhea (male and female) is accomplished with same treatment schedules as for uncomplicated gonorrhea.

**Retreatment:** The National Center for Disease Control, Venereal Disease Branch, U.S. Dept. H.E.W. recommends:

Test cure procedures at approximately 7-14 days after therapy. In the male, a gram-stained smear is adequate if positive; otherwise, a culture specimen should be obtained from the anterior urethra. In the female, culture specimens should be obtained from both the endocervical and anal canal sites.

Retreatment in males is indicated if urethral discharge persists, 3 or more days following initial therapy and smear or culture remains positive. Follow-up treatment consists of 4.8 million units aqueous penicillin G procaine, I.M. divided in 2 injection sites at single visit.

In uncomplicated gonorrhea in the female, retreatment is indicated if follow-up cervical or rectal cultures remain positive for *N. gonorrhoeae.* Follow-up treatment consists of 4.8 million units aqueous penicillin G procaine daily on 2 successive days.

Syphilis: all gonorrhea patients should have a serologic test for syphilis at the time of diagnosis. Patients with gonorrhea who also have syphilis should be given additional treatment appropriate to the stage of syphilis.

**Composition:** Each disposable syringe 2,400,000 units (4.8 size) contains penicillin G procaine in a stabilized aqueous suspension with sodium citrate buffer, and as w/v approximately 0.5% lecithin, 0.5% carboxymethylcellulose, 0.5% povidone, 0.1% methylparaben, and 0.01% propylparaben. The multiple-dose 10-ml. vial contains per ml. 300,000 units penicillin G procaine in a stabilized aqueous suspension with sodium citrate buffer and approximately 7 mg. lecithin, 2 mg. carboxymethylcellulose, 3 mg. povidone, 0.5 mg. sorbitan monopalmitate, 0.5 mg. polyoxyethylene sorbitan monopalmitate, 1.2 mg. methylparaben, and 0.14 mg. propylparaben.

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On the average, you can figure the incidence of VD among teenagers at about 900 per 100,000 population* And growing.

Among those in the 20-24 age-group, the incidence is even higher. And it, too, is growing.

In the long run, a populace educated to the risks and prevention of VD is probably the best answer to the problem. Meanwhile, though, adequate doses of the recommended types of penicillin remain a formidable weapon.

# I SYPHILIS
## JECTION
# icillin® L-A
## TERILE PENICILLIN G
## NZATHINE
## USPENSION) WYETH

**hilis is preferably treated with penicillin G nzathine, which is also the drug of choice prophylaxis after exposure. Administra- of 2.4 million units (1.2 million in each tock) usually cures most cases of primary, ondary and latent syphilis with negative nal fluid.**

**dications:** In treatment of infections due to penicillin nsitive microorganisms that are susceptible to the low and prolonged serum levels common to this particular dosage Therapy should be guided by bacteriological studies (in- ing sensitivity tests) and by clinical response.

e following infections will usually respond to adequate ge of intramuscular penicillin G benzathine.—Venereal in- ons: Syphilis, yaws, bejel and pinta.

**For deep intramuscular injection only.**

**ntraindication:** Previous hypersensitivity reaction to any cillin.

**rnings:** Serious and occasionally fatal hypersensitivity (ana- ctoid) reactions have been reported. Anaphylaxis is more ent following parenteral therapy but has occurred with oral cillins. These reactions are more apt to occur in individuals history of sensitivity to multiple allergens.

ere hypersensitivity reactions with cephalosporins have well documented in patients with history of penicillin hyper- itivity. Before penicillin therapy, carefully inquire into pre- s hypersensitivity to penicillins, cephalosporins and other gens. If allergic reaction occurs, discontinue drug and treat usual agents, e.g., pressor amines, antihistamines and corti- eroids.

**Precautions:** Use cautiously in individuals with histories of significant allergies and/or asthma.

Carefully avoid intravenous or intraarterial use, or injection into or near major peripheral nerves or blood vessels, since such injection may produce neurovascular damage.

In streptococcal infections, therapy must be sufficient to eliminate the organism; otherwise the sequelae of streptococcal disease may occur. Take cultures following completion of treatment to determine whether streptococci have been eradicated.

Prolonged use of antibiotics may promote overgrowth of nonsusceptible organisms including fungi. Take appropriate measures should superinfection occur.

**Adverse Reactions:** Hypersensitivity reactions reported are skin eruptions (maculopapular to exfoliative dermatitis), urticaria and other serum sickness-like reactions, laryngeal edema and anaphylaxis. Fever and eosinophilia may frequently be only reaction observed. Hemolytic anemia, leucopenia, thrombocytopenia, neuropathy and nephropathy are infrequent and usually associated with high doses of parenteral penicillin.

As with other antisyphilitics, Jarisch-Herxheimer reaction has been reported.

**Dosage and Administration:** Venereal infections—

Syphilis—Primary, secondary and latent—2.4 million units (1 dose).

Late (tertiary and neurosyphilis)—2.4 million units at 7 day intervals for three doses.

Congenital—under 2 years of age, 50,000 units/Kg. body weight; ages 2-12 years, adjust dosage based on adult dosage schedule.

**(Shake multiple-dose vial vigorously before withdrawing the desired dose.)** Administer by **deep intramuscular injection** in the upper outer quadrant of the buttock. In infants and small children, the midlateral aspect of the thigh may be preferable. When doses are repeated, vary the injection site. Before injecting the dose, aspirate to be sure needle bevel is not in a blood vessel. If blood appears, remove the needle and inject in another site.

**Composition:** Units penicillin G benzathine (as active ingredient): 2,400,000 units in 4-ml. single dose disposable syringe. Each disposable syringe also contains in aqueous suspension with sodium citrate buffer, as w/v approximately 0.5% lecithin, 0.6% carboxymethylcellulose, 0.6% povidone, 0.1% methylparaben, and 0.01% propylparaben. 300,000 units per ml.—10-ml. multi-dose vial. Each ml. also contains sodium citrate buffer, approximately 6 mg. lecithin, 3 mg. povidone, 1 mg. carboxymethylcellulose, 0.5 mg. sorbitan monopalmitate, 0.5 mg. polyoxyethylene sorbitan monopalmitate, 1.2 mg. methylparaben, and 0.14 mg. propylparaben.

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**INDICATIONS:** Therapeutically (as an adjunct to systemic therapy when indicated) for topical infections, primary or secondary, due to susceptible organisms, as in: • infected burns, skin grafts, surgical incisions, otitis externa • primary pyodermas (impetigo, ecthyma, sycosis vulgaris, paronychia) • secondarily infected dermatoses (eczema, herpes, and seborrheic dermatitis) • traumatic lesions, inflamed or suppurating as a result of bacterial infection.

Prophylactically, the ointment may be used to prevent bacterial contamination in burns, skin grafts, incisions, and other clean lesions. For abrasions, minor cuts and wounds accidentally incurred, its use may prevent the development of infection and permit wound healing. **CONTRAINDICATIONS:** Not for use in the eyes or external ear canal if the eardrum is perforated. This product is contraindicated in those individuals who have shown hypersensitivity to any of the components. **WARNING:** Because of the potential hazard of nephrotoxicity and ototoxicity due to neomycin, care should be exercised when using this product in treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible. In burns where more than 20 percent of the body surface is affected, especially if the patient has impaired renal function or is receiving other aminoglycoside antibiotics concurrently, not more than one application a day is recommended. **PRECAUTIONS:** As with other antibacterial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs. **ADVERSE REACTIONS:** Neomycin is a not uncommon cutaneous sensitizer. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin. Ototoxicity and nephrotoxicity have been reported (see Warning section).

Complete literature available on request from Professional Services Dept. PML.

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*(Continued on Page 28)*

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Contact **Judy Aitken, Dept. of Health & Welfare—Personnel, Statehouse, Boise, ID 83720** for further information on this position and on the advantages of living in Idaho.

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*(Continued from Page 26)*

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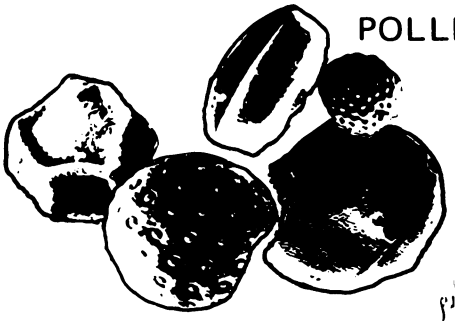

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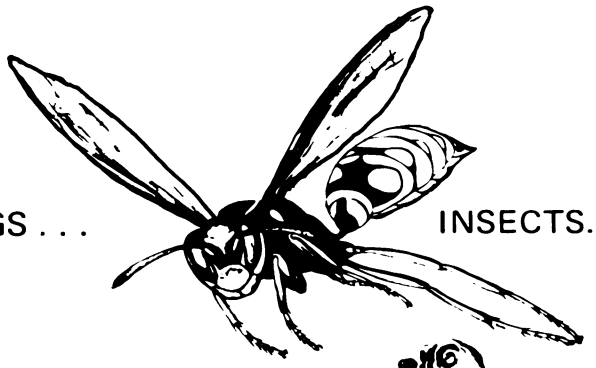

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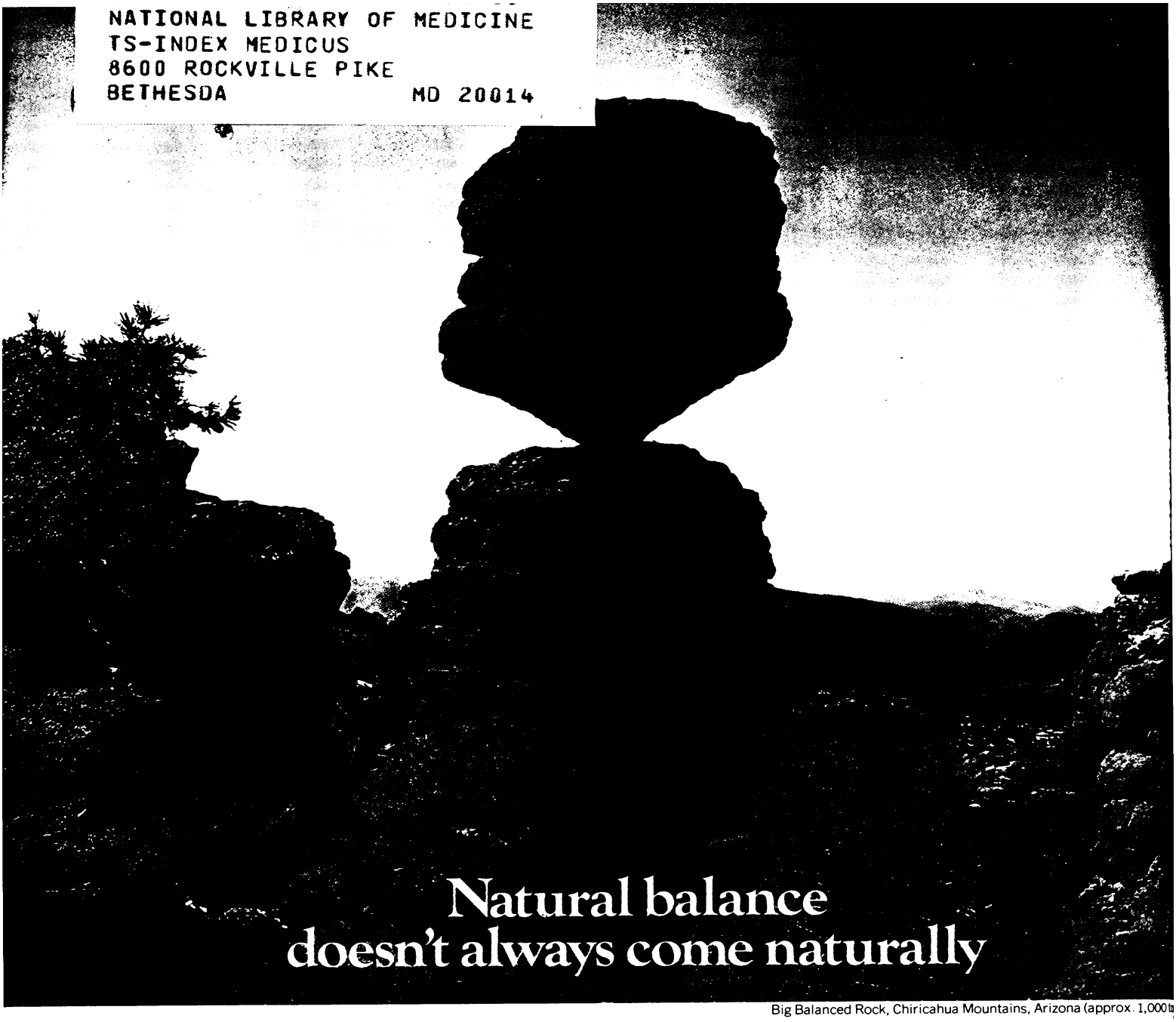

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